PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P005154-PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/BR 03/00109	International filing date *(day/month/year)* 28.07.2003	Priority date *(day/month/year)* 28.07.2003
International Patent Classification (IPC) or both national classification and IPC A61M16/04		
Applicant GRANJA FILHO, LUIZ GONZAGA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 23 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25.11.2004	26.10.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Azaïzia, M Telephone No. +49 89 2399-6960

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/BR 03/00109

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1	as originally filed
2, 2a, 2b, 3, 3a, 4, 4a, 5, 5a, 6, 6a, 7, 7a, 8, 8a, 9, 9a, 10, 10a, 11, 11a	filed with telefax on 16.06.2005

Claims, Numbers

1-14	filed with telefax on 16.06.2005

Drawings, Sheets

1/6-6/6	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,6,8-14
	No:	Claims	1,2,4,5,7
Inventive step (IS)	Yes:	Claims	13-14
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item I

Basis of the report

The present report has been established as if some of the amendments filed with telefax on 16.05.2005 had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)). The amendments concerned are the amended pages 3 to 11a of the description. There is indeed no **clear** and **unambiguous** basis in the application as originally filed for:

i. a first cuff being inflated from a conduit that is connected directly to a source coming from the respirator or another mechanism that follows the same cycle as the respirator (see amended pages 3 (lines 16-18), 7a (lines 8-11) and 8a (line 11)).
ii. the configuration of the orifices of the second and third conduits as defined on amended page 3a (lines 7-10) and amended page 4 (lines 2-7).
iii. a second cuff used mainly as a hypertension relief valve (see amended page 4, line 8 to amended page 4a, line 2, and amended pages 5 (lines 20-22), 6 (lines 14-16), 8 (lines 11-19, lines 29-32) and 10 (line 12-16 and lines 27-28)).
iv. a metallic guide located on the larger tube wall as far as its tip, or at the middle of the two tubes, and from this point to the tip of the larger tube (see amended page 6, lines 30-32)
v. a probe gage of 1/3 (see amended page 11, lines 12-22).
vi. the obtuse angle of attack of the air inlet of the conduit that communicates with the cuffs as defined on amended page 11 (line 23) to amended page 11a (line 17).

Consequently, the present report has been established as if these amendments of the description filed with telefax on 16.05.2005 had not been made, and is thus based on:

Description, pages:	
1, 3-11	as originally filed
2, 2a, 2b	filed with telefax on 16.06.2005
Claims, Numbers	
1-14	filed with telefax on 16.06.2005
Drawings, Sheets:	
1/5-5/5	as originally filed

Re Item IV
Lack of unity of invention

The present application lacks unity "a posteriori" (cf. the PCT Guidelines, III-7.5, as in force from 09 October 1998) within the meaning of Rule 13.1 PCT for the following reasons:

A. The subject-matter of claims 1 and 2 is already known from US-A-4 791 923 (cf. c.2, l.31 to l.61 - c.3, l.31 to c.5, l.44 - c.6, l.7 to l.36 - fig. 1 to fig. 5). In fact, the document US-A-4 791 923 already discloses (the references in parentheses applying to this document) a probe for medical use ("endotracheal tube 1", shown in fig.1 and fig.2) comprising:
- at least one tube ("elongated tube 2") having at least one opening ("passage 40") for receiving air insufflation; and
- a first cuff ("outer balloon 35"), arranged around the tube ("elongated tube 2") in a region of its external wall; said first cuff ("outer balloon 35") being inflatable through a first conduit ("inflation tube 26") that has an opening ("distal end portion 27") into the first cuff ("outer balloon 35") and another opening (cf. c.4, l.42 to l.53 - c.5, l.14 to l.44 - fig.2) into the interior of the tube ("elongated tube 2"); and wherein,
- the first cuff ("outer balloon 35") is located close to the end of the tube (distal end 5 of the elongated tube 2) opposite that where the opening ("passage 40") that receives air insufflation is located.

B. The requisite unity of invention (Rule 13.1 PCT) therefore no longer exists inasmuch as a technical relationship involving one or more of the same or corresponding special technical features in the sense of Rule 13.2 PCT does not exist between the subject-matter of the following groups of dependent claims:
- Claims 3-6: a probe for medical use comprising additional conduits for the suction of secretions.
- Claim 7: a probe for medical use comprising a connection means which has a switch for controlling the operation mode of the probe.
- Claims 8-10: a probe for medical use comprising a second cuff.
- Claims 11 and 12: a probe for medical use comprising means that provide the tube with an elastic memory.
- Claims 13 and 14: a probe for medical use comprising a second tube.

Actually, the special technical features of each group of dependent claims address different objective technical problems. Said problems may be regarded as being:
- a way of allowing the secretions existing inside and/or outside the probe tube to be sucked (the suction conduits of claims 3-6);
- a way of controlling the operation mode of the probe (the second connection means of claim 7);
- a way of monitoring the functioning of the first cuff (the second cuff of claims 8-10);
- a way of modifying the shape of the probe tube, such as to ease intubation or to conform more closely to the anatomy of the patient (the elastic memory means of claims 11 and 12);
- a way of permitting selective insufflation of the lungs (the second tube of claims 13 and 14).

C. Hence the International Preliminary Examining Authority considers that the following separate inventions or groups of inventions are not so linked as to form a single general inventive concept:

A. Claims 1-12: a probe for medical use comprising a first cuff inflatable through a conduit that links the interior of the cuff to the interior of the medical probe.

A.1 Claims 1, 2, 3-6: a probe for medical use comprising additional conduits for the suction of secretions.

A.2 Claims 1, 2, 7: a probe for medical use comprising a connection means which has a switch for controlling the operation mode of the probe.

A.3 Claims 1, 2, 8-10: a probe for medical use comprising a second cuff.

A.4 Claims 1, 2, 11 and 12: a probe for medical use comprising means that provide the tube with an elastic memory.

B. Claims 1, 2, 13 and 14: a probe for medical use comprising a second tube laterally coupled to the first tube of the medical probe.

This Authority found that the requirement of unity of invention is not complied with for the above-mentioned reasons and chose, according to Rule 68.1 PCT, not to invite the applicant to restrict or pay additional fees.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
   D1: US-A-4 791 923 (SHAPIRO SEYMOUR W) 20 December 1988 (1988-12-20)
   D2: EP-A-0 766 976 (SMITHS INDUSTRIES PLC) 9 April 1997 (1997-04-09)
   D3: WO-A-99/38548 (VARGAS JAIME) 5 August 1999 (1999-08-05)
   D4: US-A-5 452 715 (BOUSSIGNAC GEORGES) 26 September 1995 (1995-09-26)
   D5: WO-A-99/66975 A (PACEY JOHN A) 29 December 1999 (1999-12-29)
   D6: US-B1-6 463 927 (PAGAN ERIC) 15 October 2002 (2002-10-15)
   D7: FR-A-2 826 283 (SMITHS GROUP PLC) 27 December 2002 (2002-12-27)
   D8: US-A-5 315 992 (DALTON WILLIAM J) 31 May 1994 (1994-05-31)

2. The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of independent claim 1 is not new.
   In fact, the document **D1** already discloses (the references in parentheses applying to this document) a probe for medical use ("endotracheal tube 1", shown in fig.1 and fig.2) comprising:
   - at least one tube ("elongated tube 2") having at least one opening ("passage 40") for receiving air insufflation; and
   - a first cuff ("outer balloon 35"), arranged around the tube ("elongated tube 2") in a region of its external wall; said first cuff ("outer balloon 35") being inflatable through a first conduit ("inflation tube 26") that has an opening ("distal end portion 27") into the first cuff ("outer balloon 35") and another opening (cf. c.4, l.42 to l.53 - c.5, l.14 to l.44 - fig.2) into the interior of the tube ("elongated tube 2").
   The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

3. The subject-matter of independent claim 1 is also not new (Article 33(2) PCT) with regard to the disclosure of documents **D4** (cf. c.1, l.36 to l.62 - c.2, l.59 to c.3, l.66 and fig.1 - c.4, l.30 to l.61 and fig.3) and **D5** (cf. p.6, l.19 to p.7, l.19 - p.8, l.5 to p.9, l.9 - p.11, l.4 to l.10 - p.14, l.10 to l.17 - figures).

- The document **D4** (cf. figure 1) discloses indeed:
  - a first cuff ("inflatable balloon 5") being inflatable through a first conduit ("duct 10") that has an opening ("orifice 10a") into the first cuff ("inflatable balloon 5") and another opening ("orifice 10b") into the interior of the tube ("lumen 9 of the tube 2");

- The document **D5** (cf figure 3) discloses indeed:
  - a first cuff ("inflatable cuff 34") being inflatable through a first conduit ("entry ports 50") that has an opening into the first cuff and another opening into the interior of the tube (the entry ports 50 are formed through the wall of the tube 20 and are in fluid communication with the interior of the cuff 34);

4. Dependent claims 2 to 12 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty and/or inventive step, the reasons being as follows:

4.1 The additional features of dependent claims 2, 4 and 5 are already known from **D5** so that these claims also lack novelty (Article 33(2) PCT).
- **Claim 2:** the inflatable cuff 34 is located close to the end of the tube (distal end 37 of the tube 20).
- **Claims 4 and 5:** a third conduit ("channel 36", cf p.7, l.17 to l.19), being connectable to a suction means, has bores ("suctions ports 43") that communicate the interior of said third tube ("channel 36") with the external region of the tube ("elongated tube 20").

4.2 The additional features of dependent claims 3 and 5 are described in document **D2** (cf. c.2, l.15 to l.42 - c.3, l.3 to c.5, l.24 - fig.1 and fig.2) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include these features in the medical probe described in document **D1** in order to solve the problem posed (a way of allowing the secretions existing inside the probe tube to be sucked). Consequently, the subject-matter of claims 3 and 5 lacks an inventive step (Article 33(3) PCT).

4.3 In addition, it is pointed out that the additional features of dependent claims 4 and 5 are also described in document **D3** (the whole document) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include these features in the medical probe described in document **D1** in order to solve the problem posed (a way of allowing the secretions existing outside the probe tube to be sucked). Consequently, the subject-matter of claims 4 and 5 lacks also an inventive step (Article 33(3) PCT).

4.4 In dependent claim 6, the second conduit (which is firstly defined in claim 3) and the third

conduit (which is firstly defined in claim 4) are further defined as having one end that extends out of the tube **for coupling** (i.e. **suitable for coupling**) a connection means. This is already the case of the second and third conduits of documents **D2** (cf. point 4.2) and **D5** (cf. point 4.1) which are suitable for coupling a connection means. Consequently, the subject-matter of claim 6 do not appear to involve an inventive step (Article 33(3) PCT).

4.5 The additional features of dependent claim 7 are already known from **D1** so that said claim also lack novelty (Article 33(2) PCT).
- **Claim 7:** the first conduit of **D1** (i.e. the "inflation tube 26") is **connectable to** (i.e. **suitable for coupling**) a connection means which has a switch for controlling operation mode of the probe.

4.6 The additional features of dependent claims 8, 9, 11 and 12 are described in documents **D6** (cf. c.1, l.34 to l. 67 - c.3, l.52 to c.4, l.10 - fig. 8 and 9) and **D7** (the whole document) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include these features in the medical probe described in document **D1** in order to solve the problems posed (a way of monitoring the functioning of the first cuff (claims 8 and 9), as well as a way of modifying the shape of the probe tube, such as to ease intubation or to conform more closely to the anatomy of the patient (claims 11 and 12)). Consequently, the subject-matter of claims 8, 9, 11 and 12 lacks also an inventive step (Article 33(3) PCT).

4.7 In claim 10 a slight constructional change in the external portion of the first conduit is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of said claim lacks an inventive step.

5. The application does not meet the requirements of Article 6 PCT, because claim 13 is not clear. This claim refers indeed to the first conduit of the second tube which is not clearly defined in any of the previous claims. Nevertheless, for the purpose of this international preliminary examination report, only that combination of technical features which have **clear** and **unambiguous** a basis in the application as filed have been taken into consideration (see the description on page 10, line 31 to page 11, line 10, and fig.9). Dependent claim 13 has thus been considered as follows:

"13. A probe according to any one of claims 1 to 12, further comprising a second tube (17) laterally coupled to the first tube (1), said second tube (17) being provided with at least one opening for receiving air insufflation, a cuff being arranged around the two tubes (16, 17) in a region of their external walls and being inflatable through a first conduit (18) arranged at the second tube wall, said first conduit (18) having an opening into the interior of said cuff arranged around the two tubes (16, 17) and another opening into the interior of the second tube (17), characterised in that said first conduit (18) extends as far as the inside of the first cuff (3) of the first tube (1) and opens into the interior of the first cuff (3) of the first tube (1)". Consequently:

5.1 The document **D8**, which is considered to represent the closest prior art to the subject-matter of claim 13, discloses a probe for medical use permitting selective insufflation of the lungs (cf. c.5, l.44 to c.6, l.50 - Fig.2 and 2A) from which the subject-matter of claim 13 differs in that the first conduit of the second tube extends as far as the inside of the first cuff of the first tube and opens into the interior of the first cuff of the first tube.

A probe according to the present invention allows the selective insufflation of the lungs of a patient, wherein the inflation of the different cuffs is commanded by the flow of air injected into the tubes during the inspiratory movement, causing thereby the probe to be fixed to the walls of the patient's passageway; whereas the deflation of the same cuffs takes place when the air is expelled from the patient's lungs though the tubes during the expiratory movement. By temporarily deflating the cuffs during the expiratory phase, the present invention **alleviates the mechanical pressure on the walls of the patient's passageway and makes the blood circulation possible until a new flow of air is injected, which may come from an artificial breathing apparatus or from the normal breathing of the patient.**
This alternative solution to the problem of the selective insufflation of the lungs proposed in claim 13 of the present application is new (Article 33(2) PCT) and cannot be derived in an obvious manner (Article 33(3) PCT) from the documents cited in the international search report.

5.2 Claim 14 is dependent on claim 13 and as such also meets the requirements of the PCT with respect to novelty (Art. 33(2) PCT) and inventive step (Art. 33(3) PCT).

6. The subject-matter of claims 1 to 14 is considered industrially applicable since it can be

made or used in any kind of industry (Article 33(4) PCT), such as the medical industry for example.

----- Certain defects in the international application -----

7. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document **D8** is not mentioned in the description, nor is this document identified therein.

7.1 The document US-A-5 452 715 (=**D4**) is incorrectly identified in the description as "US Pat. 5,452,71**6**" (see the description on page 2, line 31).

tance pump that uses cuffs for blocking the aorta and the coronary arteries in diastole. According to that patent, the passageway for blood from the aorta is kept opened by means of a system of two cuffs that are sequentially inflated and deflated, the sequence being determined by signals from an electrocardiogram apparatus, which are used as commands for sequentially inflating and deflating the two cuffs for the purpose of never interrupting the flow of blood in the aorta, which would obviously cause the death of the patient. This solution, however, besides being specific for use in the aorta, is of technically complex construction, needing two cuffs and, chiefly, imposing an artificial rhythm of opening and closing the blood-circulation passageway, which is undesirable from the physiological point of view.

US Pat. 4,791,923 deals with a tracheal probe composed of an outer cuff and an inner cuff, the latter being located inside the outer cuff, said cuffs being non-physiologically inflated by conduits. Since they are very thin, they only work under high pressure; besides, these cuffs do not inflate, if they are connected to the lumen of the tube. This probe has the purpose of sealing the trachea completely with the outer cuff during inspiration and expiration in pressure peaks, without letting the gases leak. However, due to the elasticity of the trachea and its consequent dilatation, the inflated gases leak.

EP-A-0,766,976 describes a probe with only a suction system that only sucks the interior of the tube. This probe prevents contamination and respiratory problems during the suctions, as well as carries out these suctions uninterruptedly. Since it has an internal cannula for uninterrupted suction, the probe lumen is reduced. Said probe dispenses with the use of a connector with the Y for introduction of the suction catheter.

WO-A-99/38548 deals with a probe that has a lumen dedicated to the suction trigger for aspirating secretions from the trachea. This probe does not have a valve, or tap, for connection of the internal and external aspirations; these aspirations could be effected simultaneously or alternatively, in case the probe had a valve.

US Pat. 5,452,716 describes a tracheal tube for assisting the breathing of patients with respiratory insufficiency, as long as they are with

their breathing under control.

Document WO-A-99/66975 describes an intratracheal ventilation catheter. In this catheter, the whole sucked air passes though the cuff, with the air flowing to the distal end of the catheter until it reaches the trachea, and the expired air is made outside the tube. In this instrument, the outlet for air from the cuff is the same air inlet.

US Pat. 6,463,927 describes a guide for an endotracheal tube made from a plastic material containing a bendable rod.

FR-A-2,826,283 deals with an endotracheal medical surgical probe adaptable only to the morphologies of oral regions and external segments of the patients' mouth.

Objectives of the Invention

An objective of the present invention is to prevent injuries caused by prolonged intubation of a patient with a probe provided with an inflatable cuff.

Another objective of the present invention is to provide more tranquility to the physician in performing surgeries that require a longer time for intubating the patient, as well as to provide a probe suitable for facilitating intubation in emergency situations.

A further objective of the present invention is to prevent possible injuries caused by inserting the metallic thread into the tube in order to conform the probe.

The invention has also the objective of preventing the use of a pharyngoscope.

A further objective of the present invention is to prevent the cuff from being excessively inflated, which would cause injuries to the patient.

Another objective of the invention is to provide a probe especially for patients who remain intubated for a long time, independently of its duration.

The above-described objectives of the invention are achieved by means of the probe that will be described in greater detail later.

Summary of the Invention

The present invention has achieved the above-cited objectives by means of a probe for medical use, which basically consists of a tube designed for receiving blown air, and a first cuff arranged around the tube in a region of its external wall, said first cuff being inflatable by means of a first conduit located at the tube wall, which account for communication of the inside of the first cuff with the inside of the tube. Thus, the insufflation of the

first cuff is commanded by the flow of air injected into the tube during the inspiratory movement, causing the probe to be fixed to the walls of the passageway of the human body that is being intubated; whereas the deflation of said first cuff takes place when the air is expelled from the patient's lung through the tube during the expiratory movement. This causes the first cuff to deflate temporarily, thus alleviating the mechanical pressure on the walls of said passageway of the human body and making blood circulation possible until a new flow of air is injected, which may come from an artificial breathing apparatus or from the normal breathing of the patient.

Thus, said first cuff is inflated during the inspiration and deflated during the expiration at the natural rhythm of the patient's respiration or artificial breathing apparatus. In this way the above-mentioned problems of the prior art are eliminated and the probe of the present invention has an ideal performance from the physiological point of view. Further, said first cuff may be inflated from a conduit that is not connected to the tube lumen, but rather to one of the legs of the Y connector, connected to the probe or else directly from a source coming from the respirator or another mechanism that follows the same cycle of the respirator.

According to a preferred embodiment of the invention, the probe further comprises means that provide the tube with an elastic memory, located on the tube wall and consisting of a guide thread made from a radiopaque flexible and malleable material. Such means simultaneously allow one to mold the probe tube and to view the probe on an X-ray photograph, for instance, besides enabling one to mold the probe, adapting its exit to the mouth, nose or tracheostomy orifice, to prevent known lesions caused by probes to lips, gums, teeth, tongue, nose wings and neighboring structures of the tracheotomies. These means having elastic memory enable a simple, rapid non-traumatic intubation, and even without laryngoscope.

According to another embodiment of the invention, the probe for medical use comprises, in addition to the tube, the first cuff and the first conduit in the tube wall that communicates the interior of the tube with the interior of the cuff, a second and a third conduits in the tube wall, which extend

along the length of the tube and are able to be coupled to an external aspiration device.

The second conduit has bores close to an end, which provide communication of the inside of the second conduit with the inside of the tube, the other end being connectable to a suction device, thus allowing the secretions existing inside the probe tube to be sucked, which prevents the tube from being clogged. The orifices remain in the back wall of the tube 1, at a distance of 1 centimeter from each other and extend from the cuff to the distal end of the tube. Their diameters are equal to or smaller than that of the conduit that has given rise to them.

The third conduit, on its turn, has bores close to one of its ends, which provide communication of the inside of the third conduit with the exter-

nal region of the tube, the other end being connectable to a suction device, so that the secretions existing inside the tube can also be sucked. The orifices also remain in the back wall of the tube that is related to the back wall of the trachea, have a diameter equal to or smaller than that of the conduit that has given rise to them, and are in number of three in the oropharynx and three in the trachea, over the cuff 1 by one centimeter when the latter is totally inflated, and are away from each other by 1.5 centimeters.

In addition, the second and third conduits are connectable by their ends to a first 3-way connection means, coupled to the external suction device and provided with a switch that permits suction at each of the conduits separately or at both conduits at the same time. In this way, depending upon the position of the switch, either the secretions existing inside the tube alone can be sucked (through the second conduit) or the secretions existing in the external region of the tube (through the third conduit), as well as the secretions of both regions at the same time.

According to an embodiment of the present invention, the first conduit is connectable to a second 3-way connection means, provided with a switch that enables one to control the operation mode of the probe. In this way, the probe may also be used in the conventional manner, with non-physiological pressure, depending upon the position of the switch. In this case, the cuff is inflated by injecting a fluid into one of the ways of the connection means and remains permanently inflated.

The probe is further provided with a second monitoring cuff, located around the first conduit, also linked to the inside of the first conduit in the region close to the opening of the tube that receives air insufflation, which is inflated and deflated at the same rhythm as the inflation and deflation of the first cuff takes place. The second cuff is used for monitoring the functioning of the first cuff, since it will only be inflated if the first cuff is intact. It is use mainly as a hypertension relief valve, since the cuff is elastic and extensible, absorbing any excess pressure, so that the cuff, at most, only rests against the trachea without damaging it. The trachea is more resistant than the satellite cuff. For this reason, the satellite cuff expands and even blows out in ca-

ses of too high pressure, making impossible the barotraumas over the trachea walls.

Another probe embodiment is also provided, the probe having two tubes coupled side by side, one of them being longer than the other, permitting selective insufflations of one lung, for example, by connecting an artificial breathing apparatus to one of the probe tubes and simultaneously inflating the first cuffs of each tube, the first cuff of the first tube being close to the bronchia, and the first cuff of the second tube being in the trachea region, surrounding the two tubes altogether. For this purpose, the air outlet of the tube cuff that is not connected to the artificial breathing apparatus should be kept closed. If, on the other hand, one wishes to effect the selective inflation of the other lung, for example, one

connects the artificial breathing apparatus to the other tube, closing the air outlet of the tube cuff that is not connected to said breathing apparatus.

Brief Description of the Drawings

Figure 1 shows a cross-section view of a first embodiment of the probe for medical use of the present invention, the figure illustrating the probe tube, the first cuff, the first conduit located at the tube wall, having an opening into the interior of the first cuff and an opening into the interior of the tube, as well as the means that provide the tube with an elastic memory, which consists of a radiopaque flexible rod in the preferred embodiment of the invention, which extends throughout the whole tube.

Figure 2 is a top view from the AA' section of the first probe embodiment illustrated in figure 1, which shows the first cuff, the first conduit, located at the tube wall along the length of the tube, and the radiopaque flexible rod.

Figure 3 shows a cross-section view of a second probe embodiment according to the present invention, the figure illustrating the probe tube, the first cuff, the first conduit located at the tube wall, having an opening into the interior of the first cuff and an opening into the interior of the tube, the radiopaque flexible rod and the second cuff, which monitors the functioning of the first cuff, and absorbs the excess pressure of the system, thus preventing hypertension in the first cuff and, consequently, tension of the first cuff in the trachea.

Figure 4 is a cross-section view of a third probe embodiment of the present invention, illustrating, in addition to the components described in figure 3 (probe tube, first cuff, first conduit located at the tube wall with an opening into the interior of the first cuff and a second opening into the interior of the tube, radiopaque flexible rod and second cuff), the connection means, which enables the probe to be used as a conventional probe, with active inflation of the first cuff by means of a syringe, or else with passive inflation of the first cuff at the moment of inspiration with the physiological pressure of the airways, the backflow of air during expiration being immediately closed, thus maintaining the first cuff permanently inflated, but with physiological

pressure.

Figure 5 shows a cross-section view of a fourth embodiment of a probe for medical use, which illustrates the probe tube, the first cuff, the first

conduit located at the tube wall, having an opening into the interior of the first cuff and an opening into the tube, the radiopaque flexible rod, the second and third conduits, provided with bores and arranged at the tube wall, through which the secretions existing inside and outside the probe tube are sucked, the first and second connection means, as well as the second cuff for monitoring the first cuff.

Figure 6 is a top view from the BB' section of the fourth probe embodiment illustrated in figure 5, which shows the first cuff, the first conduit, the second conduit and the third conduit, located at the tube wall along the length of the tube, as well as the radiopaque flexible rod throughout the whole tube.

Figure 7 is a cross-section view showing, in detail, the second cuff, which communicates with the first conduit, which accounts for monitoring the first cuff, besides being one of the main mechanisms of protection of the trachea wall, since it prevents hypertension in the first cuff, which is elastic, distensible and has low resistance in its filling.

Figure 8 is a cross-section view of a fifth embodiment of the probe of the present invention, illustrating, in addition to the components described in figure 5 (probe tube, first cuff, first conduit, radiopaque flexible rod, second and third conduits, first and second connection means and second cuff), the detail of a portion of the first conduit that is connected to the second cuff and which is external to the tube wall and concertina, whereby its length may be adjusted if it is necessary to cut the probe or increasing it.

Figure 9 shows another embodiment of the probe for medical use with the same characteristics of the above-described embodiments, but further comprising a second tube similar to the first one, laterally coupled to the first tube, having a shorter length than the latter and a first conduit that communicates the interior of the second tube with the interior of the first cuff of the second tube, said first conduit extending as far as the inside of the first cuff of the first tube. The metallic guide remains located on the larger tube wall as far as its tip, or at the middle of the two tubes, and from this point to the tip of the larger tube.

Detailed Description of the Figures

Figure 1 illustrates a first embodiment of the probe for medical use of the present invention. This first embodiment comprises a tube 1, provided with at least one opening 2 to receive air insufflations, and a first cuff 3, arranged around the tube 1 in a region of its external wall, which is inflatable

by means of a first conduit 5 arranged at the wall of the tube 1, having an opening into the interior of the first cuff 3 and another opening into the interior of the tube 1. The inflation of the first cuff 3 occurs by injecting a flow of air into the opening of the tube of the probe 2 during the inspiration, bringing about the fixation of the probe to the walls of the passageway of the human body that is being intubated and principally sealing or occluding the trachea, so that inspired air will not escape. The deflation of the first cuff 3, in turn, occurs in the period of time in which air is expelled from the patient's lungs through the probe tube 1, that is, during the expiration, providing a relief of the mechanical pressure that was being exerted by the first cuff 3 on the walls of said passageway of the human body and making blood circulation possible in this region until a new flow of air is injected into the human body. Thus, the inflation and deflation of the first cuff 3 take place following the rhythm itself of the patient's respiration (inspiration and expiration, respectively), which makes the probe physiologically ideal. It should be pointed out that the flow of air insufflated into the tube 1 of the probe may also come from an artificial breathing apparatus, on patients with mechanical ventilation or any ventilation mode, including awake patients breathing spontaneously with probe or tracheotome.

In addition, figure 1 shows the means 4 that provide the probe tube 1 with an elastic memory, located at the tube wall along the length of the tube 1. Such means 4 consist of a guide thread made from a flexible and radiopaque material, which enables one to mold the probe tube 1 and to view the probe in an X-ray photograph and to effect tracheal intubation without the use of a laryngoscope with patient's head and neck in any angulations and/or position. This prevents serious injuries to lips, gums, teeth, nose wings and tracheostomy orifices, besides molding the probe at the exit of the mouth and/or nose and /or tracheostomy orifice, or else other cannulas such as artery and vein cannulas used in heart surgeries or any other types of surgery which needs a flexible plastic tube with elastic memory.

This elastic memory imparts to the tube an important purpose: making it a first option in emergency procedures such as CRA (cardio respi-

ratory arrest) and/or polytraumatisms and facial and cervical injuries, because it dispenses with the guide thread and the laryngoscope.

Figure 2 is a top view from the section AA' of the first probe embodiment illustrated in figure 1. In this figure, one illustrates the first cuff 3, arranged around the tube 1, and the first conduit 5, located at the tube wall along the length of the tube, which has an opening into the interior of the first cuff 3 and a second opening into the interior of the tube 1 or else into the interior of a preferably Y-shaped connector coupled to the tube 1, or else coupled to an independent source from the respirator that has a cycle in the same rhythm of the breathing or else specific equipments for inflating and deflating the cuffs, synchronically with the cycle of the respirator.

Figure 3 illustrates a second probe embodiment for medical use, which also consists of a tube 1, which will receive air insufflation; a first cuff 3, arranged around the tube 1, in a region of its external wall, said first cuff 3 being inflatable by means of the conduit 5 arranged at the tube wall, having an opening into the interior of the first cuff 6 3 and another opening into the

interior of the tube 1; and means 4 that provide the probe tube 1 with an elastic memory, located at the tube wall along the length of the tube 1. It should be pointed out that the inflation and deflation of the first cuff 3 are effected by following the procedure described above for the first probe embodiment for medical use.

The probe of this second embodiment, illustrated in figure 3, is further provided with a second cuff 16 for monitoring, which is also linked to the inside of the first conduit 5 in the region close to the opening 2 of the tube that receives air insufflation and is inflated and deflated together with the first cuff 3. The second cuff 16 monitors the functioning of the first cuff 3, and is only inflated if the first cuff 3 is intact. This satellite cuff 16 is elastic and extendable, working mainly as relief valve for any excess pressure in the tracheal and bronchial cuffs, so that the most that can happen is for the cuffs to rest against the trachea, and never press upon them; since the satellite has less resistance it will expand, absorbing the excess pressure. It the pressure is too great, the satellites will expand until they blow out and, event so, no injury will be caused to the trachea by the cuffs; which will only rest against it. This means that the trachea has much higher distension than the satellite cuffs.

Figure 4 illustrates a third probe embodiment for medical use, comprising the same elements of the probe embodiment of figure 3, described above. The inflation and deflation of the first cuff 3 is effected by the same procedure of the embodiment of the preceding figure.

In the probe embodiment of figure 4, the first conduit 5 is connected to a connection means 20, provided with a switch that enables one to control the probe operation mode. In this way, the probe may also be used in a conventional manner, with non-physiological pressure, the first cuff 3 being inflated, in this case, by insertion of a fluid and remaining permanently inflated even if it is inflated with high pressure, the one that will absorb the excess pressure is the satellite cuff and not the first cuff, that it to say, in any form of functioning there will never be hyperpressure in the cuffs against the wall of the bronchia and trachea. The probe will further be used

with passive inflation of the first cuff 3 at the moment of inspiration, with the physiological pressure of the airways, the backflow of air and deflation of the first cuff 3 being prevented by closing the connection means 20. In this way, the first cuff 3 remains permanently inflated, but with physiological pressure of the airways.

Another embodiment of the probe for medical use is shown in figure 5, which also comprises a tube 1, which will receive air insufflation; a first cuff 3, arranged around the tube 1 in a region of its external wall, said first cuff 3 being inflatable through a first conduit 5 arranged at the tube wall, having an opening into the interior of the first cuff 3 and another opening into the interior of the tube 1, or from and direct spurce of respirator, or from Y connected to the probe or a specific equipment to inflate and deflate the cuffs with low pressure, synchronically with the cycle of the respirator. The inflation and deflation of the first cuff 3 are effected by following the same procedure described above for the first em-

bodiment of a probe for medical use.

Figure 5 also shows the means 4 that provide the probe tube 1 with an elastic memory, located at the tube wall along the length of the tube 1, consisting of a guide thread made from a flexible and radiopaque material 5 that permits the molding of the probe tube 1, the viewing probe in an X-ray photograph and the tracheal intubation without the use of a laryngoscope, and principally in emergencies for intubation, such as CRA (cardio respiratory arrest), polytraumatisms, facial and cervical injury, urgency tracheostomy, facilitates and expedites greatly the intubation procedure, since it dispenses with the guide and even the laryngoscope, minutes or seconds less, which may represent the patient's life, also preventing the risks of injures caused by conventional guides and laryngoscope when effected by inexperienced people, such as breaking teeth, laceration of the gums, tongue, oropharynx, perforation of the oropharynx, stomach, trachea, bronchia, larynx, vocal cords and underlying organs such as the aorta.

In addition, the probe embodiment shown in figure 5 further comprises a second conduit 8 and a third conduit 10, located at the tube wall and extending along the length of said tube 1, said second conduit 8 being provided with bores 9 close to one of its ends, linking the interior of the tube with the interior of the second conduit 8, whereas the other end is couplable to an external suction means, and the third conduit 10 being provided with bores 11 close to one of its ends above the tracheal cuff, linking the interior of the third conduit 10 to the external region of the tube 1, while the other end of the third conduit 10 is couplable to an external suction means which may be automatic, continuous, intermittent or manual, effected by the physician himself or paramedical. In this way, the secretions existing inside the tube 1 and in the external region of the tube 1 may be sucked through the second 8 and the third 10 conduits, respectively, thus preventing any obstruction of the passageway for the flow of air that may be caused by the presence of such secretions. The second 8 and third 10 conduits are also connectable to a first 3-way connection means 12, provided with a switch 13 for controlling the

suction of secretions through the second 8 and third 10 conduits 10, said first connection means 12 being coupled to an external suction means. Depending upon the position of the switch 13, either the secretions located inside the tube 1 alone or those located in the external region of the tube 1 alone can be sucked, or the secretions of both the regions can be sucked at the same time.

According to an embodiment of the present invention, the first conduit 5 is connectable to a second 3-way connection means 14, provided with a switch 15 that enables one to control the probe operation mode. In this way, the probe may also be used in the conventional manner, with non-physiological pressure, depending upon the position of the switch 15, the first cuff 3 being inflated, in this case, by inserting a fluid into one of the ways for

the second connection means 14, and remaining permanently inflated, or else with passive inflation of the first cuff 3 at the time of inspiration, with physiological pressure of the airways, the backflow of air and the deflation of the first cuff 3 being prevented by closing the connection means 14. In this way, the first cuff 3 remains permanently inflated, but with the physiological pressure of the airways.

The probe shown in figure 5 is further provided with a second cuff 16 intended for monitoring, located around the first conduit 5, also linked to the interior of the first conduit 5 in the region close to the opening 2 of the tube that receives air insufflation, which is inflated and deflated in conjunction with the first cuff 3. The second cuff 16 monitors the functioning of the first cuff 3 and is only inflated if the first cuff 3 is intact and is one of the elements responsible for the specially non-traumatic nature of this probe, since it is elastic and distensible, prevents, in any circumstance, the occurrence of hyperpressure in the cuffs, thus preventing the risk of ischemia or mechanical trauma of the trachea by the cuff (preventing barotraumas).

Figure 6 is a top view from the section BB' of the probe embodiment illustrated in figure 5. This figure illustrates the first cuff 3, the first conduit 5, the second conduit 8 and the third conduit 10, arranged at the tube wall along the length of the tube.

Figure 7 shows a second cuff 16 similar to the first one 3, which communicates with the first conduit 5 and is inflated and deflated in conjunction with the first cuff 3. The second cuff 16 is located close to the end of the tube where the opening 2 that receives air insufflation is located. The second cuff 16 is inflated and deflated at the same rhythm of the inflation and deflation of the first cuff 3, being used for monitoring the first cuff 3, since its inflation will only occur if the first cuff 3 is intact and functions as a relief valve for pressure peaks, since it is elastic and distensible.

Figure 8 illustrates a fifth embodiment of a probe for medical use, which comprises the same elements and has the same operation mode of the probe embodiment of figure 5, described above. However, in this probe embodiment, the first conduit 5 has a concertina portion 21 outside the tube

wall, close to the end connected to the second cuff 16. In this way, the length of the first conduit 5 may be adjusted, if it is necessary to cut the probe in order to reduce the dead space or else increase it in order to increase the dead space.

Figure 9 shows another embodiment of a probe for medical use with the same characteristics of the embodiments described above, but fur-

ther comprising a second tube 17, similar to the first one 1, that is to say, being also provided with at least one opening for receiving air insufflation, and a first cuff arranged around the two tubes 1 and 17 in a region of their external walls, inflatable through a first conduit 18 arranged at the tube wall 17, having an opening into the interior of the first cuff and another opening into the interior of the tube 17, this first conduit extending as far as the inside of the first cuff 3 of the first tube 1. The inflation and deflation of the first cuff of the second tube 17 and of the common tracheal cuff that involves the two tubes occurs in the same way described previously for the first cuff 3 of the first tube 1. This second tube 17 is laterally coupled to the first tube 1 and is shorter than the fist tube 1.

The conduits 5 and 18 which communicate the inside of the probe with the cuffs and that carry part of the inspired air to inflate them, should compulsorily show expansion at the rate of about 1/3 of the probe gage, being located at the thickness of the probe wall, so that they will project inwards or outwards. This great gage, quite larger than that of conventional probes, will cause the air-flow resistance to be low and the cuffs to be inflated long before the air reaches the end of the probe, guaranteeing that the trachea will be sealed and preventing waste of the inspired gases. If the gage of these conduits is small, equal to that of conventipnal probes, the resistance is great and the cuffs will not be inflated and so the whole air inspired will leak around the probe, making it ineffective and inadequate for use.

In addition, the location of the air inlet of these ducts has to be either at the proximal end of the probe or at a Y-connector, never near the cuff, be it tracheal or bronchial, for the following reasons:

a) being distant, the cuff will inflate long before the air inspired reaches the probe tip, thus preventing waste of gas. When the volume of air inspired represents the double volume of air in the cuff, the latter will be filled, and the air has only reached the extent of the probe that holds the same volume, that is to say, never having reached the tip. This is very important, since otherwise the cuff does not inflate sufficiently to seal the trachea and permit ventilation with positive pressure;

b) the air inlet of the conduits that communicate with the inside of the probe as cuff may never be at the most distal end of the probe, near the cuff. In this case, the air inspired would reach the tip of the probe at a high speed and, instead of inflating the cuff, the air will suck it by the Venturi effect, drying it even more. The probe would be completely ineffective, since the cuff would not inflate. Moreover, even if the cuff inflated a little, this would be for a short time, since this location and the size of its orifice would be factors that would lead to its obstruction rapidly, as well as to an almost immediate flooding of the cuff chamber by secretions, which would make the probe ineffective;

c) the angle of attack of the air inlet of the conduit that communicates the cuffs with the tube lumen may never be in the direction contrary to the flow of inspired air, not even at a 90-degree angle. It has to form an obtuse angle with respect to the outer surface of the tube, that is to say, it has to be in the same direction of the inspired air with the legs of the Y. This is fundamental, otherwise the inspired air upon passing through the orifice will generate a Venturi effect, which will aspire the cuff and not inflate it.

It should be understood that the probe for medical use and its components described above are only a few embodiments that might exist. The real scope of the object of the invention is defined in the accompanying claims.

CLAIMS

1. A probe for medical use characterized by comprising:

at least one tube (1) having at least one opening (2) for receiving air insufflation; and

a first cuff (3), arranged around the tube (1) in a region of its external wall; said first cuff (3) being inflatable through a first conduit (5) that has an opening into the interior of the first cuff (3) and another opening into the interior of the tube (1).

2. A probe according to claim 1, wherein the first cuff (3) 15 located close to the end of the tube (1) opposite that where the opening (2) that receives air insufflation is located.

3. A probe according to claim 2, comprising a second conduit (8) at the tube wall, which extends along the length of the tube (1), being connectable to an external means, and having, close to one of its ends, bores (9) that communicate the interior of the tube with the interior of said second conduit (8).

4. A probe according to claims 1, 2 or 3, further comprising a third conduit (10) at the tube wall, which extends along the length of the tube (1), being connectable to an external means, and having, close to one of its ends, bores (11) that communicate the interior of said third conduit (10) with the external region of the tube (1).

5. A probe according to claims 3 or 4, wherein the external means is a suction means.

6. A probe according to claims 3, 4 or 5, wherein each of said second (8) and third (10) conduits has another end that extends out of the tube (1) for coupling a first connection means (12), which has a switch (13) for controlling the suction at said second (8) and third (10) conduits and being coupled to a suction means.

7. A probe according to any one of claims 1 to 6, wherein said first conduit (5), which links the interior of the first cuff (3) to the interior of the tube (1), is connectable to a second connection means (14), which has a switch (15) for controlling the operation mode of said probe.

8. A probe according to any one of claims 1 to 7, comprising a second cuff (16) linked to the interior of the first conduit (5) to be inflated and deflated in conjunction with the first cuff (3), located close to the end of the tube (1) where the opening (2) that receives air insufflation is located.

9. A probe according to claim 8, wherein the first conduit (5) is a passageway made in the wall of the tube (1), having a portion outside the wall of the tube (1).

10. A probe according to claim 9, wherein said external portion of the conduit (5) is concertina shaped (21) close to the end connected to the second cuff (16).

11. A probe according to any one of claims 1 to 10, comprising means (4) that provide the tube (1) with an elastic memory, located along the wall of the tube (1).

12. A probe according to claim 11, wherein said means (4) that provide the tube (1) with an elastic memory are radiopaques.

13. A probe according to any one of claims 1 to 12, further comprising a second tube (17) laterally coupled to the first tube (1), wherein the first conduit (18) of the second tube extends as far as the inside of the first cuff (3) of the first tube (1).

14. A probe according to claim 13, wherein said second tube (17) is shorter than the fist tube (1).